Exhibit 11

RESPONSIVE EXPERT REPORT OF DR. MARK PAPICH

I. Background

1. I have been a veterinary clinical pharmacologist for over 25 years. I obtained my D.V.M. from Colorado State University in 1982, and my M.S. in Clinical Pharmacology from the University of Illinois in 1985. I have held veterinary licenses in Colorado, Illinois, California, and Saskatchewan Canada. I have a current veterinary license in the state of North Carolina. I am board-certified in the specialty clinical pharmacology by the American College of Veterinary Clinical Pharmacology (ACVCP).

2. I have been on the faculty in the Department of Molecular Biomedical Sciences in the College of Veterinary Medicine at North Carolina State University (NCSU) since 1993. I was appointed as Associate Professor from 1993-2001, and promoted to Professor of Clinical Pharmacology at NCSU in 2001. In 2009, I was awarded the American Academy of Veterinary Pharmacology & Therapeutics Teaching Award in recognition of 25 years devoted to teaching veterinary professional and graduate students and the Legends in Collaboration Award from Kansas State University in recognition of excellence in clinical pharmacology. In 2008, I was awarded the Huffman Leadership Award in recognition of outstanding contributions to NCSU College of Veterinary Medicine.

3. As a Professor of Clinical Pharmacology, my teaching duties include responsibility for undergraduate and graduate courses in Veterinary Pharmacology, Pharmacology and Veterinary Therapeutics, and Principles of Pharmacology and direct a clinical pharmacology rotation of senior veterinary students. I have personally supervised and trained six graduate students in veterinary pharmacology, and was a member of the graduate committee for an additional 20 other graduate students. I have personally trained five diplomates in the specialty

of veterinary clinical pharmacology (ACVCP), which is more than any other member of this specialty. My research activities have been focused on pharmacokinetics, antimicrobial therapy, analgesic drugs, and analytical methodology.

4. I am an author (or co-author) of over 200 publications and am on the editorial board of a number of journals, including the *Journal of Feline Medicine and Surgery*, *Veterinární Medicína* and the *Journal of Veterinary Pharmacology and Therapeutics* (to which I also serve as an editor for review articles). I have given hundreds of invited lectures and courses all over the world, including locations in North America, South America, Australia, Europe and Asia. I am a Fellow in the American Academy of Veterinary Pharmacology and Therapeutics and a member of the American Society of Clinical Pharmacology and Therapeutics (ASCPT).

5. A list of my publications in the last 10 years is provided in Appendix 1.

6. I have written or edited 5 books that deal with veterinary pharmacology and drug therapy in animals. I am one of the editors of the 9th Edition of Veterinary Pharmacology and Therapeutics, which is a textbook used world-wide to teach veterinary pharmacology. I have authored several papers that have specifically focused on pharmacokinetics of antimicrobials, including tetracyclines, used in animals. I have written two textbook chapters on tetracycline antimicrobial drugs, including the most recent chapter in the 9th Edition of Veterinary Pharmacology and Therapeutics. I have delivered dozens of invited lectures to veterinarians and scientists at national and international conferences and symposia that serve as a guide on the proper use and dosing of antimicrobials, including tetracyclines, in animals.

7. I have acted as the President and Chairman of the Board of the American College of Veterinary Pharmacology and Therapeutics. I have held a position on the Veterinary Medicine Advisory Committee for the Food and Drug Administration (FDA). Additionally, I

was elected to the Council of Experts for the United States Pharmacopeia (USP)[1] for two 5-year terms, and served as the Chairman of the Veterinary Drug Expert Committee at the USP for ten years. I have been a voting member of the Veterinary Antimicrobial Susceptibility Testing (VAST) subcommittee of the Clinical Laboratories Standards Institute (CLSI), for ten years and currently serve as the Vice Chair of the VAST.

8. In addition to my university-related activities, I have provided confidential consulting services to pharmaceutical companies. My advice is generally sought on new drug development for medications used in animals.

II. Mandate

9. I have been asked by counsel for Pennfield Oil Company to provide an opinion on the Complaint (Civil No. 8:09CV345) Pennfield Oil Company vs Alpharma Inc.

10. I have reviewed the Complaint, depositions, and other supporting documents provided to me by the counsel for Pennfield Oil Company. In forming my opinions, I have relied on these materials with specific focus on Exhibits A-D and G cited in the Complaint. I have also relied on published information on the pharmacology of tetracyclines, textbooks, the United States Pharmacopeia, and pharmacokinetic references, as well as my training and experience. I have also been supplied with additional Deposition Exhibits by the Pennfield counsel, which I have referred to in my report. These Exhibits consist of study reports, published papers, and correspondence between the study investigators and individuals at Alpharma Inc.

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[1] The USP is a non-governmental entity that provides official standards in the United States, Canada, and approximately 130 countries across the globe. USP sets standards for the quality, purity, strength, and consistency of prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States.

11. During the last four years, I have testified as an expert at trial or by deposition in the following cases:

a. In the Matter of Wedgewood Village Pharmacy, DEA docket # 04-08 (2008)

12. I am being compensated for my time at my usual rate of $250 per hour. My compensation is in no way dependent on the outcome of this case.

III. Summary of Opinions

13. My opinion in this report is based on a reasonable degree of scientific certainty as a veterinary clinical pharmacologist. Using these criteria, the Exhibits A-D, and G provided in the complaint contain flawed scientific studies and analysis. The studies cited in the Exhibits are not performed with sufficient scientific depth, rigor, accuracy, and assurance that would qualify these studies as scientifically reliable. The exhibits contain false, deceptive, and misleading advertising and promotion of oral chlortetracycline feed additives for pigs. These promotional materials attempt to give the impression that there is an advantage for the Aureomycin premix chlortetracycline medications over other brands. In my opinion, the promotion contained in these advertisements are not supported by scientific evidence using a reasonable degree of certainty and analysis of the studies.

14. The specific advertisements are provided in Exhibits A and G, and a "Pork Facts" article provided in Exhibit B. The information put forth in these promotional materials is apparently based on studies conducted at the University of Montreal and presented in partial form in Exhibits C and D. Exhibit C has the title "Therapeutic lung exposure to feed-administered chlortetracycline is premix brand dependent" written by Drs. del Castillo and Wolff.

15. The advertising and promotional exhibits are based on unpublished data. The studies cited that were conducted at the University of Montreal were presented in the

Proceedings of the American Association of Swine Veterinarians in 2006 (Exhibit C). Conclusions from the same study were presented in an abstract presented in the Proceedings of the 19th IPVS Congress in Copenhagen, 2006 (Exhibit D). Meeting proceeding papers and abstracts are not refereed publications and should not be cited as such. Without being subject to a review of the scientific community (review by peers), the results and conclusions of such a study cannot be accepted without challenge. To cite these papers in the promotional materials and advertisements as "university studies" is deceptive and misleading. All scientists – particularly those in academia – realize that without scientific scrutiny and review by one's peers in a published scientific periodical, data from studies should not be accepted as scientifically legitimate. These data were originally presented in 2006, but four years later (2010) these results have still not been published in a scientific peer-reviewed journal. I personally have attended the IPVS meeting (Vancouver 2010) and I have had a presentation and study accepted for publication at the American Association of Swine Veterinarians (meeting scheduled for March 2011). I realize from my first-hand experience that there is no scientific scrutiny or peer review of the studies published in the proceedings and presented in oral communication at these meetings. For any scientist to suggest, as Dr. del Castillo has done in his deposition, that the proceedings from these meetings are peer-reviewed before publication is false, misleading, and deceptive. I serve on the Editorial Board of several refereed journals, I have published many articles in refereed journals, and I have served as a reviewer many times. I am fully aware – and any scientist on the faculty of a University is aware – of the peer-review process that is used before valid scientific studies are published.

16. There are numerous flaws and errors made in the Methods in the studies that are the focus of the materials cited in the Complaint. The summary of these Methods are listed in pages 143-144 of Exhibit C. Among the errors and misrepresentations are:

a. It states that the study was "double-blinded". A blinded study is one in which the investigator analyzing the data is not aware of the treatment allocation. Because Dr. del Castillo acknowledged in his deposition that the code was revealed before the data analysis was completed, this study was not blinded. Therefore, the statement is false. Double-blinded suggests that the pigs were also not aware of the treatment, which is ridiculous to state in a veterinary study. Ordinarily "double-blinded" refers to human studies in which the person treated as well as the physician, are not aware of the treatment.

b. It states that Experiment #1 used USP standard dissolution testing methods, and cites General Chapter <1088> (listed as reference #8). As the Chairman of the USP Veterinary Drug Expert Committee, and a member of the USP Council of Experts for 10 years, I believe that I am an authority on USP standards for veterinary drugs. For the analysis of chlortetracycline premix in feed, no such standard exists. Therefore, this statement is also false. Furthermore, General Chapter <1088> is simply an informational chapter, not a standard method. To imply that a standard USP method exists for dissolution testing of veterinary dosage forms, misrepresents the intent of USP methods and is a misuse of the data generated. USP drug dissolution methods are only standardized for human dosage forms. The human dissolution testing methods cannot be accepted for testing veterinary dosage forms because of multiple factors, including important physiological differences between animals and humans.

Testing monographs in the USP/NF exist only for chlortetracycline hydrochloride tablets, and include a method for testing disintegration, not dissolution[2]. Moreover, even if a standard USP method was used for this study, Drs. del Castillo and Wolff violated the standard of the procedure by performing the study using feed material. This is never done with dissolution testing of human drugs.

c. The investigators reported only one pH was used for dissolution testing. A range of pH values must be tested to simulate the fluid in the gastrointestinal tract. Drugs are not absorbed from the stomach; they are absorbed from the intestine. Whether or not the drug dissolves in simulated gastric fluid is irrelevant. Many drugs are insoluble in gastric fluid (for example BCS Class II drugs), but are completely absorbed after transit to the intestine. Typically, at least 3 pH values should be used for testing (pH of 1.2, 4.6, and 7.5) according to US-FDA Guidance #171[3]. Although these are non-binding recommendations and to be used only as a guide to industry sponsors, this document is currently the only guideline available that contains specific recommendations for testing of premix medications for swine.

d. If indeed a USP method was used, their own results belie the validation of their assay. The USP dissolution testing of an immediate-release oral formulation requires that the formulation perform with at least 85% release within 15-30 minutes. Yet, the investigators acknowledge that the Aureomycin formulation only released 66% of the drug after 120 minutes of testing. The Aureomycin product failed the test, which

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[2] USP/NF United States Pharmacopeial Convention. USP32/NF27 2009. United States Pharmacopeia 12601 Twinbrook Parkway, Rockville, MD, page 1920, Volume 2.

[3] US-FDA Guidance for Industry #171. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (CVM), October, 6, 2008.

invalidates this method for any additional testing and considerations. Lack of a validated *in vitro* test for these formulations should completely nullify any results or conclusions that are derived from these tests.

e. The authors imply that the USP dissolution testing methods provide evidence for the performance of medications *in vivo*. Such a conclusion is false and a misuse of the USP testing methods. The USP general chapter <1088> that is cited by del Castillo and Wolff in Exhibit C and D, as well as in the promotional materials and advertisements, states clearly and without ambiguity that *in vitro* dissolution tests of oral dosage forms should not be used to predict the *in vivo* pharmacokinetic performance of a medication [4]. In fact, in vitro-in vivo correlations (IVIVC) are almost never possible with oral immediate release formulations. Dissolution studies are only useful as a guide in formulation development or as a production quality control procedure. It is a gross misuse of these dissolution data to associate *in vitro* dissolution with *in vivo* performance.

f. Page 144 of the Materials section states that oral absorption was modeled using "zero order" absorption. Oral absorption of medications from the gastrointestinal tract is typically first order. Analyzing the data as zero order would likely produce errors in the results. Zero-order input implies a constant source of drug (for example administered at a constant rate). However, the methods of the study describe the drug dosing to the pigs was administered via separate distinct meals. Drs. del Castillo and Wolff acknowledge later in the paper (bottom of page 146 Exhibit C) that, in fact, the

[4] General Chapter <1088> In Vitro and In Vivo Evaluation of Dosage Forms. United States Pharmacopeia, USP32/NF27. United States Pharmacopeia, 1201 Twinbrook Parkway, Rockville, MD. Page 556-557, 2009.

oral absorption of the medication in this study was first-order. Therefore, they acknowledge that their analysis did not represent the proper model for this data. These results should therefore be disregarded by anyone knowledgeable of pharmacokinetic methods.

g. The analysis of the therapeutic effect was performed by assuming that tetracyclines are time-dependent antibiotics (second column of page 144). In fact, the PK-PD properties are predicted by the area-under-the-curve (AUC) in comparison to the MIC (AUC/MIC), not time above MIC [5]. In another paper written by Dr. del Castillo in 2002, he also acknowledges that the PK-PD parameter for assessing efficacy of tetracyclines is not known[6]. On page 108 of that paper, the authors write that, "Although tetracyclines do not exhibit concentration-dependent killing, the AUC/MIC ratio is the major PK/PD parameter correlating with the therapeutic efficacy of these drugs". Therefore, the use of the parameter of time above MIC in the paper by del Castillo & Wolff in 2006 (Exhibit C), is false, misleading and a misuse of PK/PD parameters. This was known, or should have been known, to be false because of prior publication in 2002. Other authoritative sources have also concluded that AUC/MIC, not time above MIC, is the appropriate parameter for assessing efficacy of tetracyclines. In the textbook, Veterinary Pharmacology and

[5] Agwuh KN, MacGowan A. Pharmacokinetics and pharmacodynamics of the tetracyclines including glycylcyclines. J Antimicrob Chemother. 2006 Aug;58(2):256-65.

[6] Toutain PL, Del Castillo JRE, Bousquet-Melou A. The pharmacokinetic-pharmacodynamic approach to a rational dosage regimen for antibiotics. Res Vet Sci 73: 105-114, 2002.

Therapeutics, 9th edition [7], a book used world-wide as an authority in veterinary pharmacology, it states on page 896, "Based on an evaluation of tetracycline PK-PD, the effectiveness is best expressed as a ratio of the area-under-the-curve for a 24 hour interval to the MIC (AUC/MIC)". Because the misuse of the time above MIC parameter is such a critical cornerstone on which the *in vivo* study analysis is based, any conclusions based on this analysis must be disregarded as invalid and without basis.

17. There are numerous misrepresentations, errors, and omissions in the Results section of the studies that were the basis of the conclusions made by Drs. del Castillo and Wolff cited in the Complaint. These results are provided on pages 144-146 of Exhibit C. Among these are:

a. No pharmacokinetic results are presented. There is no reviewer of a pharmacokinetic study that would accept such a paper. The authors proposed to conduct a pharmacokinetic study, but by not listing the results that are critical components of a pharmacokinetic study, the authors have misrepresented the investigation. This omission would not pass as a pharmacokinetic study by any reasonable scientist and would not be accepted by a peer-reviewed journal. At the very minimum, important parameters such as the concentrations measured, AUC, maximum concentration (Cmax), time of peak (Tmax), and half-life should be reported. Without these results presented, it is impossible to draw reasonable conclusions and provide analysis of these data. These studies should be regarded as invalid until such data are provided.

[7] M.G. Papich & J.E. Riviere. Chapter 35. Tetracycline Antibiotics. *in* Riviere JE and Papich MG (Editors). Veterinary Pharmacology and Therapeutics, 9th Edition. Wiley-Blackwell Publishing, Ames, Iowa, USA. 1524 pages; 2009.

b. The authors del Castillo and Wolff have selectively reported their results. This is known as "cherry-picking" of the data by scientists. It is not accepted by the scientific community and is a transparent attempt to conceal important data from the audience. Examples of selective reporting of data are: in Figure 1, the results of only one part of the *in vitro* study, but not the second part; they did not report critical pharmacokinetic values; they did not provide a figure of plasma concentrations; they did not list the comparison of AUC ratios among the formulations tested; and they completely omitted the results from Experiment 1.

18. There are numerous flaws, misrepresentations, and errors in interpretation of the data that was discussed in the Discussion section of the Exhibits. Because the conclusions made in the Discussion section are important to the assumptions endorsed in the advertising and promotional materials, these require illumination. The Discussion section is provided in pages 146-147 of Exhibit C. Among these are:

a. They state that the results confirm that CTC interacts with feed particles. No such evidence was presented. If CTC indeed were to interact with feed particles, this interaction would be independent of feed premix brand.

b. They imply that the premix formulations are generic brands. The formulations tested in this study are not generic brands as implied in the title of the advertising materials.

c. The authors acknowledged that some pigs fed the Pennchlor brand did not eat the feed supplemented with the medication. It is absolutely scientifically invalid to compare the results of a pharmacokinetic study between formulations when the animals may have received different doses. If the medicated feed was not consumed by some pigs, then it is obvious that they did not receive the same dose. Any further

comparison of formulations from the *in vivo* study should be nullified and disregarded.

d. Conclusions from the pharmacokinetic study were made from a comparison of the *variability* in the time above MIC, not on the absolute time above MIC, nor on other critical parameters. This is yet another example of "cherry picking" the data to present results that are misleading and deceptive. The absolute percent time above MIC should have been compared among formulations, which obviously would not have been different. In fact, percent time above MIC is not different among formulations which drastically alters the results presented in the Exhibit's advertising and promotional materials.

19. The most prominent feature that draws readers to the promotional materials is the title, which often provides the first impression to an audience. In each and every exhibit provided, the title is false, misleading and a misrepresentation of the studies described.

a. Exhibit A: "Granular CTC Premixes are Not Created Equal". This statement is misleading and absurd. Obviously every premix on the market is manufactured under different conditions, with excipients that may vary with each formulation. Indeed, it is stating the obvious to point out that they are not "created equal". But the tone of the advertisement implies that they perform differently or that one product is superior to another. There is absolutely no evidence presented in the advertisement or citations in the advertisement that supports a suggestion that quality or performance among the chlortetracycline premix products are different.

b. Exhibit A: "Aureomycin vs Generics". The other formulations tested were not "generics".

c. Exhibit G: "Aureomycin . The granulated, broad-spectrum, antibacterial, that remains unsurpassed in quality, potency, and most important therapeutic action". Chlortetracycline is not broad spectrum. It is a narrow-spectrum drug. It is not unsurpassed in the features listed. In fact, no evidence was presented to show that it surpasses other formulations in any of the categories tested. In tests revealed in Experiment #1, Aureomycin was inferior. No therapeutic trials were conducted. It is absolutely impossible to imply that the Aureomycin formulation was superior therapeutically without a well-conducted therapeutic trial in pigs with disease.

20. The Implications from the studies as listed on page 147-148 of Exhibit C are among the most obvious misrepresentations which form the basis of the promotions made for Aureomycin formulations. Each and every one of the bullet points listed in the *Implications* section can be disregarded because it is false, misleading, or a selective interpretation of the data. For example:

a. The *in vitro* studies absolutely must be disregarded because of the use of a non-validated method, an absurd application of the standard USP dissolution methodology, and selective reporting of data.

b.Pl asma therapeutic concentrations were *not* maintained more consistently with the Aureomycin preparations because a definition of "therapeutic plasma concentration" was never established.

c. The *in vitro* results compared the variability in plasma concentrations, not the absolute concentrations achieved.

21. **Data contained in the Full Report**: The full report of the study on which the data in Exhibits C and D was based is contained in Exhibit 25 (labeled as Report – Version #2)[8]. This full report contains several data and observations that were either not revealed, or intentionally concealed from the advertising materials in Exhibit A, B and G. These data were also either not reported, or intentionally concealed from the report in Exhibit C and D. Because these data and conclusions were not reported in the Exhibits cited above, it violates the scientific validity of the claims made in those Exhibits. Furthermore, the additional data available in Exhibit 25 renders the conclusions in Exhibit A-D, and G as misleading, false, and intentionally deceptive. Specific data presented in Exhibit #25 are worth highlighting below:

a. On page 9 of the report, are the results from Experiment #1. The investigators reported that, "Comparison of the CTC kinetic profiles from each medicated feed suggests that premix B (Aureomycin 220) was considerably less effective in providing therapeutic CTC plasma concentrations in a larger number of pigs".

b. On page 10 of the report, the investigators wrote that, "premixes A, C, and D (A = Pennchlor, B = Chlor 100; D = Aureomycin A90) seemed comparable to each other, with a slight advantage for Premix D in terms of maximum plasma concentration, and for Premix A (Pennchlor) in terms of median duration at concentrations greater than 0.5 mg/L."

c. On page 11-12 of the report, the measure of absolute bioavailability is reported. Any qualified veterinary pharmacologist with training and experience knows that the true measure of the extent of oral drug absorption is

[8] Deposition Exhibit 25, Bates # 1290

the fraction absorbed (listed as "F"). This is usually represented as a percent and is the fraction of oral dose absorbed, compared to an intravenous dose as determined by a ratio of AUC values. The data from Experiment #1 shows that oral bioavailability of CTC was highest for the Pennchlor medication, but was not significantly different among all formulations.

d. Page 11, Table 3 of the report shows that the Pennchlor formulation produced a higher duration of time above MIC, which was statistically significant ($p = 0.017$). Therefore, the investigators misrepresented the time above MIC parameter that is the basis for Figure 3 of Exhibit C in the Complaint.

e. Results from Latin Square #2 are reported in pages 11-13 of the report. Again, the authors concluded that the Aureomycin 220 premix was "less effective in releasing its content in CTC and providing therapeutically effective concentrations in plasma, as indicated by its lower F, and almost significantly shorter Duration (time above MIC)".

f. The omissions of these data from the Exhibits contained in the Complaint represent selective and deceptive reporting of data. This is an egregious violation of scientific ethics and should be condemned.

22. Correspondence by the investigators revealing the difficulties with the studies.

a. In the Deposition Exhibits[9], e-mail correspondence between the investigators on the studies reveals in the investigators own words, "Teddi, I have just finished calculating the bioavailability estimates, corrected for

[9] Deposition Exhibits 11, 12, 13, 19, 20.

differences in potency and carryover. .... Pennchlor shows better after correcting for potency and Aureo 220G is still the last".

b. In several e-mail messages from the investigator to the study monitor, the investigator acknowledges the problems with the pharmacokinetic models. These models have not been validated and appear to be highly subject to interpretation and bias. It appears that the investigator attempted model-after-model (Exhibit 11) until he found one that provide the answers they were looking for. Evidence for this biased approach in pharmacokinetic modeling is provided in the e-mail of 7/15/2005 (page # 0830) in which the investigator acknowledged to the study monitor, "In this set of data, plasma concentrations peak surprisingly late, so the generic kinetic models prove inadequate to find the answers we are looking for."

23. **Reporting of Tissue Concentrations:** In the Exhibits presented in the complaint, as well as in the full report (exhibit 25, pages 13-15) the investigators have reported tissue lung concentrations of CTC. These concentrations are obtained by first euthanizing the pigs, collecting the tissue homogenates, and then analyzing concentrations based on whole tissue analysis. This method of reporting antibiotic concentrations is misleading and deceptive.

a. This practice has been condemned by highly reputable scientists [10], in which they state that, "A common method is to use measurements of concentrations in tissue homogenates, comparing these with values derived from the corresponding blood samples and on that basis draw

[10] Mouton JW, Theuretzbacher U, Craig WA, Tulkens PM, Derendorf H, and Cars O. Tissue concentrations: do we ever learn?Journal of Antimicrobial Chemotherapy (2008) 61, 235–237

conclusions with respect to the potential clinical use of the drug. This approach is not justifiable for a number of reasons that includes both pharmacokinetic as well as pharmacodynamic causes. This way of presenting data with the derived conclusions is often misleading and may ultimately be harmful in patient care."

b. This method of reporting drug concentrations has been criticized and challenged by Dr. del Castillo and his coauthors in a paper published in 2002 [11]. In that paper, they stated, "There is a persistent inclination in veterinary medicine to report ''total tissue concentrations'' for some antibiotics (especially macrolides) and to argue that this ''tissue level'' is better related to efficacy than the plasma concentration. However, this point has been challenged because the total tissue concentration determined after homogenization may be very different from the biophase concentration whatever its location (intra- or extracellular)."

c. On the basis of these and other sources, the data and conclusions in the Exhibits based on lung concentration data should be totally and completely disregarded.

IV. Conclusion:

I have analyzed the Complaint, Exhibits made available to me, and other supporting documents that are the basis of the Complaint. I have concluded that the claims made in the advertisements and promotional materials are indeed false, deceptive, and misleading. The advertisements and promotional materials for Aureomycin products are biased and not supported

[11] Toutain PL, del Castillo JR, Bousquet-Mélou A. The pharmacokinetic-pharmacodynamic approach to a rational dosage regimen for antibiotics. Res Vet Sci. 2002 Oct;73(2):105-14.

by scientific evidence using a reasonable degree of certainty and relying on my training and experience in veterinary pharmacology. The data from the studies are not scientifically reliable, and the methods are flawed. These errors and omissions occur throughout Exhibits A-E and G and are not confined to only certain sections, one aspect of the analysis, or contained in just some of the conclusions. They are persistent, and cannot be excused because of minor errors, unintentional omission, or lack of attention to detail. Therefore, there appears to be a deliberate and consistent attempt to mislead and deceive the audience for which these materials are intended

November 1, 2010

Mark G. Papich

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